

### Summary of Part D Application Revisions

Clarification	Purpose of the Clarification	Application		
		PDP	MA-PD	Cost
GENERAL INFORMATION				
Adds new dates for the Bid and Formulary Training conferences.	The original applications gave a date of Late March for the conferences. They have now been scheduled for April 4 and 5 in Washington D.C.	1.4	1.4	1.4
INSTRUCTIONS				
Changes the contact name for mailing applications to CMS.	Employee turnover requires us to change the contact name for the applications.	2.6	2.5	2.4
Adds a new section under 2.6 entitled, “ Joint Enterprise as Applicant and Contracting Entity”. Further, requires that each organization comprising the joint enterprise submit its own subcontracts, compliance plan, and a detailed plan on the joint enterprise operating as a single entity, ensuring a seamless benefit to the beneficiary and full accountability to CMS.	Consistent with Title I regulation correction of the preamble, indicates what information a joint enterprise must provide.	2.6	2.6	n/a
Clarifies that Section 3.10, the Compliance Plan Section of the application, needs to be submitted on the cd with the Business Integrity information.	This reference was mistakenly dropped from the MA-PD application.	n/a	2.5	n/a
Amends the date for when CMS will notify Applicants regarding waiver approval along with their application approval from late April to May.	Needed to reconcile this date with other references throughout the application that Applicants would be notified in May.	n/a	2.12	2.12
APPLICANT EXPERIENCE, CONTRACTS, LICENSURE AND FINANCIAL STABILITY				
Adds to Section 3.1.1 (management and operations) instructions to submit a certification that all required contract elements are included in the Applicant’s subcontracts, as well as an excel chart noting citations from the subcontracts that crosswalk to each specific contract requirement.	Will significantly simplify and make quicker the CMS review of contracts.	3.1.1G 3.1.1H	3.1.1E 3.1.1F	3.1.1E 3.1.1F
Clarifies in 3.1.1D that the term for executed subcontracts for Year One to begin November 15, 2005.	The initial application specified that the subcontracts should be at least the first year of the program; however, for 2006 the functions must be in place by November 15, 2005—the first date of the annual election period for the 2006 benefit.	3.1.1D6	3.1.1D6	3.1.1D6
Deletes an attestation in 3.1.2 (experience and capabilities) that concerns a required number of individuals enrolled for the first	This attestation reflects a future year statutory requirement, not a Year One requirement.	3.1.2A8	3.1.2A8	3.1.2A8

year of the program.				
Adds an instruction in 3.1.3 (licensure and solvency) that Applicants submit copies of proof of state licensure documentation.	This documentation will significantly reduce the time needed to verify with States whether applicants are licensed as they claim.	3.1.3D	n/a	n/a
Amends the attestation in the Business Integrity section by removing the reference to any major shareholder (of 5% or more).	CMS has questionable authority to deny an applicant where a 5% shareholder appears on the HHS exclusion list.	3.1.4	3.1.3	3.1.3
<b>BENEFIT DESIGN</b>				
Requires documentation in the P&T Committee Member Chart in Section 3.2.1C of the members who are practicing physicians, practicing pharmacies, and experts in the care of the elderly and the disabled.	This clarification is necessary for a complete review by CMS.	3.2.1C	3.2.1C	3.2.1C
Deletes the forms requesting contact information for individuals responsible for the utilization management programs, quality assurance and patient safety programs and the medication therapy management programs.	The information asked for in these forms are duplicative of information that is already being collected through HPMS.	3.2.2B 3.2.3C 3.2.4C	3.2.2B 3.2.3C 3.2.4C	3.2.2B 3.2.3C 3.2.4C
Clarifies that attestations, not answers to descriptive questions, are due on March 23, 2005. The descriptive questions concern: 1) approach to formulary transitions; 2) approach to accommodate discrepancies between Part D formulary and LTC facility COPs; 3) MTM program descriptions; 4) components to MTM fees, if any to be paid to providers.	Answers are due to CMS on April 18, 2005 to provide more time for thorough responses.	3.2.3A 3.2.4A	3.2.3A 3.2.4A	3.2.3A 3.2.4A
<b>SERVICE AREA/REGIONS</b>				
Clarifies the directions that only those intending to offer a Regional PPO should complete the attestation table related to Service Area/Regions in the MA-PD application.	The original application incorrectly asks all MA-PD applicants to complete this section.	n/a	3.3A	n/a
Adds a table requiring applicants to identify the service area/regions that they plan to serve under the Part D benefit.	This information is necessary to conduct a Fallback Service Area analysis.	3.3B	3.3B	n/a
<b>PHARMACY ACCESS</b>				
More clearly states when pharmacy access, work plans, and pharmacy lists are due to CMS.	The revisions clarify that only retail pharmacy information is due 03/23/05 and the other types of pharmacy information are due 08/01/05.	throughout 3.4	throughout 3.4	throughout 3.3

Adds instruction under Pharmacy Access to complete an excel chart demonstrating where in the Applicant's contracts the pharmacy network requirements are met.	Will significantly simplify and make quicker the CMS review of contracts.	3.4	3.4	3.3
Corrects that subcontracting requirement 3.1.1F14 in the PDP application, and 3.1.1D14 in the MA-PD and Cost applications does NOT apply to pharmacy contracts.	Corrects a mistake in the original application.	3.4B	3.4B	3.3B
Provides definitions of urban, suburban and rural areas. Lists website locations for CMS data files needed to complete access analyses.	Making convenient to the applicant, information that is already available through other channels.	3.4.1B	3.4.1B	3.3.1B
Insert attestation under Out of Network Pharmacy that application agrees to have adequate access to Part D benefits dispensed in physician's office.	This is a correction. This attestation is already in the PDP and MA-PD applications	n/a	n/a	3.3.2A2
Adds an attestation clarifying that Applicants are required to ensure that their network contracts address delivery of Part D drugs in the home setting through home infusion pharmacies.	CMS will examine pharmacy contracts for delivery of drugs in the home setting.	3.4.4A3	3.4.4A3	3.3.4A3
Deletes the EXAMPLES of performance and service criteria to be included in LTC contracts. Instead, the instruction points the Applicant to forthcoming LTC guidance.	CMS' LTC Guidance will be available in early March, and we want to avoid any confusion as to what list of performance and service criteria must be in the LTC pharmacy contracts.	3.4.5A1	3.4.5A1	3.3.5A1
Removes requirement for access maps and tables; retains explanation of how convenient access will be assured.	CMS plans to conduct analyses in 2006 that determines using claims and other data that institutionalized beneficiaries are receiving drugs through Part D plans' LTC network pharmacies.	3.4.5D	3.4.5D	3.3.5D
Specifies the elements that the Applicant's work plan for LTC pharmacy contracting must cover.	Providing this instruction helps assure that the work plan will be satisfactory to CMS.	3.4.5C	3.4.5C	3.3.5C
Adds an attestation in the I/T/U Pharmacy section on whether the Applicant's service area/region includes I/T/U pharmacies.	Will prevent CMS from erroneously finding the an application as incomplete when I/T/U documentation is not included.	3.4.6A	3.4.6A	3.3.6A
Specifies the elements that the Applicant's work plan for I/T/U pharmacy contracting must cover.	Providing this instruction helps assure that the work plan will be satisfactory to CMS.	3.4.6C	3.4.6C	3.3.6C
<b>EXCEPTIONS, APPEALS AND GRIEVANCES</b>				
Adds attestations on Grievances.	Rather than assume that Part C grievance policies and procedures will be updated by the Applicants to include Part D, we make explicit what are the expectations to address grievance requirements specific to Part D.	n/a	3.5B	3.5B

<b>TRACKING OUT-OF POCKET COSTS (TrOOP)</b>				
Deletes an attestation related to Applicants providing CMS with quarterly aggregate TrOOP calculations.	CMS does not have a need to collect these data from plan sponsors on a quarterly basis.	3.9A5	3.7A5	3.7A5
<b>MARKETING/BENEFICIARY COMMUNICATIONS</b>				
Revises an attestation in the Marketing/Beneficiary Communication section that updates the types of materials applicants will need to send enrollees in accordance with developing subregulatory guidance.	Better informs the Applicant of the nature of the the attestation.	3.10	3.8	3.8
<b>PRIVACY</b>				
Adds Privacy attestations into the MA-PD application.	Rather than assume that Part C privacy policies and procedures will be updated by the Applicants to include Part D, we make explicit this expectation.	n/a	3.14	n/a
Adds additional Privacy attestations into the Cost application.	Rather than assume that privacy policies and procedures will be updated by the Applicants to include Part D, we make explicit this expectation.	n/a	n/a	3.13
<b>SECURITY AND RECORD RETENTION</b>				
Adds Security and Record Retention attestations into the application.	Rather than assume that Security and Record Retention policies and procedures will be updated by the Applicants to include Part D, we make explicit this expectation.	n/a	3.15	3.15
<b>APPENDICES</b>				
Revised waiver tables to remove references to waivers that in fact are not waivers but rather Part D requirements that are deemed met.	More accurately reflects what is a waiver.	n/a	Appendix V	Appendix IV
Provides additional guidance in the Financial Solvency Documentation in Appendix X in the PDP application. Clarifies the following on calculating projected losses: 1) applicant must demonstrate sources of funding sufficient to cover the greater of 7.5% of the aggregated projected target costs, or 100% of projected losses if that amount is higher than the 7.5% of aggregated projected target costs; 2) what sources of funding can be counted for this purpose.; and 3) clarifies the definition for subordinated debt.	This guidance clarifies how CMS will determine what is sufficient funding to cover losses, and also demonstrates that these funds must scale to the size of the plan.	Appendix X	n/a	n/a
Appendices added related to revised requirements above to submit crosswalks from subcontracts to the Part D requirements.	Will significantly simplify and make quicker the CMS review of subcontracts.			